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10/553,007	08/07/2006	Claude Mialhe	0518-1161	1299

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EXAMINER	
OU, JING RUI	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,007	MIALHE, CLAUDE	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on September 11, 2008. Claims 1-16 are pending. Claim 1 is independent.

Claim Objections

2. Claims 1-16 are objected to because of the following informalities: the term "device" in the preamble of each claim should be replaced by "system" since claim 1 includes an implant and an apparatus for delivering the implant.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the expandable element (24)" in paragraph 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vargas et al (US Pub. No. 2002/0042622).

In regard to Claims 1-5, 11, 15 and 16, Vargas et al discloses an implant delivery system, comprising: a vessel dilation device (deployment system 150 excluding anastomosis device 120, Fig. 5) with an outer envelope (outer trocar, 152, Fig. 5) and a tapered end piece (tapered end piece of 152, Fig. 5), whereby the end piece consists of a nose (the tapered end piece of 152 is a nose), means for opening the nose, consisting of at least two longitudinal slots which divide the nose into several segments (Figures 5 and 6 and Para. [0062]); an implant (anastomosis device 120, Fig. 5), the implant includes an expandable element (distal end of 120 presses against the internal wall of the distal end of the outer envelope when 120 is pushed out of the 152, Fig. 5) which presses against the internal wall of the outer envelope; means of translation, the means of translation include an inner sheath (holder tube, 154, Fig. 5); the implant includes a second, hollow expandable element (shoulders 134, Fig. 5) and a hollow intermediate section (the intermediate section of 120 must be deformation by twisting, Fig. 5); a grip (distal fitting, 184, Fig. 5) that is an integral part of the outer envelope; a grip (medial fitting, 184, Fig. 5) that is an integral part of the inner sheath, and a plunger (expander tube, 156, Fig. 5).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Garza et al (US Pat. No.: 4,665,918) in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claims 1-16, Garza et al discloses an implant delivery system, comprising: a vessel dilation device (combination of prosthesis delivery catheter 18, sheath 50, and guiding catheter 78, Fig. 1) with an outer envelope (guiding catheter, 78, Fig. 1); an implant (prosthesis, 25, Fig. 5), the implant includes an expandable element (distal portion of the prosthesis, Fig. 5); means of translation, the means of translation include an inner sheath (sheath, 50, Fig. 5); the implant includes a second, hollow expandable element (the proximal end of the prosthesis 25, Fig. 5) and a hollow intermediate section (the intermediate section of the prosthesis 25 is deformable be twisting since it is an expandable stent, Fig. 5); a grip (hub, 86, Fig. 1) that is an integral part of the outer envelope; a grip (hub, 64, Fig. 1) that is an integral part of the inner sheath, a removable spacer (locking arms 72, Fig. 7, the combination of the locking arms 72 and 44 restrict the relative positions of hub 86 and hub 64 and a portion of locking arms 72 is situated between the hubs 86 and 64), a plunger (combination of proximal portion 22 and portion 24, Fig. 1), a grip (hub, 30, Fig. 1) that is an integral part

of the plunger, a second removable spacer (hubs, 44, Fig. 7), means (the separated portions 58 is capable of rotating the inner sheath and thus adjusting the angle of the inner sheath) of adjusting the angle of the inner sheath, and a central channel (the channel of guiding catheter, Fig. 1) along the line of the outer envelope.

Garza et al does not appear to disclose that the outer envelope has a tapered end piece and detailed structures of the end piece.

However, Martinez et al explicitly discloses an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath, whereby the end piece consists of a nose (the tapered distal end portion 32 is nose, Fig. 1) and means for opening the nose, consisting of at least two longitudinal slots (weakened areas, 41-45, Fig. 2A) which divide the nose into several segments (sections, 51-55, Fig. 2A), nose segments are joined as required along the slots when the nose is closed (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); temporary connector by slots between segments (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); and the nose includes a central residual passage (central opening, 50, Fig. 2A).

Garza et al and Martinez et al are analogous art because they are from the same field of endeavor, implant delivery system.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Garza et al and Martinez et al before him or her, to

modify the implant delivery system of Garza et al to include an outer envelope having a tapered end piece and detailed structures of the end piece as taught by Martinez et al.

The suggestion/motivation for doing so would have been to protect the implant from premature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42). Applicant should have noted that the tapered end piece is old and well-known in the art. Furthermore, it is old and well-known that the nose include a shape memory, which would facilitate the withdrawn of the delivery system from body or enable insertion of another implant without withdrawing the sheath out of the body.

Therefore, it would have been obvious to combine Martinez et al with Garza et al to obtain the invention as specified in the instant claims.

Response to Arguments

9. Applicant's arguments filed 09/11/2008 have been fully considered but they are not persuasive.

In response to the allegation on page 8 of the remarks, the term "device" in the preamble of each claim should be replaced by "system" since claim 1 includes an implant and an apparatus for delivering the implant.

In response to applicant's argument on pages 9 and 10 of the remarks that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the claimed device is easier and quicker to

use" and "the variation in the diameter of the expandable element followed the variation in diameter of the nose, avoiding the 'jump' when implant is release") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The allegation on page 10 of the remarks that Vargas does not or "cannot" disclose the claimed outer shell or envelop to contain an expansible element of the implant is incorrect. The distal end of the outer envelope is capable to contain the expansible element of implant or anastomosis device 120 (Fig. 5).

The allegation on page 10 of the remarks that the devices of Garza et al and Martinez et al are unrelated is incorrect. Both Garza et al and Martinez et al are analogous art because each of them discloses an implant delivery system.

The allegation on page 10 of the remarks that there would have been no reason to combine Martinez et al with Garza is incorrect. The suggestion/motivation for modifying the outer envelope Garza to have a tapered end piece and detailed structures of the end piece would have been to protect the implant from premature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42).

The allegation on page 11 of the remarks that the stent delivery apparatus of Martinez et al does not allow the use of a guide wire is incorrect. A guide wire (Martinez et al, 12) is disclosed to be used with stent delivery apparatus (Martinez et al, Fig. 1).

In response to applicant's argument in page 11 of the remarks that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the opening of the nose by the stent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The limitation "the expandable element (24) can press against the internal wall of the nose (14) in order to open out the segments (15a, 15b, 15c, 15d)" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/Julian W. Woo/
Primary Examiner, Art Unit 3773

October 23, 2008